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05/185 551	05/16/96	ISRAEL	FIRST NAMED INVENTOR	R	ATTORNEY DOCKET NO.
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18M1/0807

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CAPUTAS EXAMINER

ART UNIT

PAPER NUMBER

08/07/97

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/466,381

Applicant(s)
Israeli

Examiner
Anthony C. Caputa

Group Art Unit
1817



☒ Responsive to communication(s) filed on Jun 16, 1997

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 90-93 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 90-93 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Applicants amendment was received 7/22/97 as Paper No. 27. Claims 93-96 renumbered as claims 90-93 by Rule 126 are pending.

2. Claims 90-93 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses SEQ ID NO. 2 which corresponds to the nucleic acid sequence encoding the prostate specific antigen having the amino acid sequence shown in SEQ ID NO. 2. This SEQ ID No. 2 meets the written description and enablement provisions of 35 U.S.C. 112, first paragraph. However the claims are directed to encompass a nucleic acid molecule (i.e. primer) that hybridize to the nucleic acid sequence encoding the prostate specific antigen having the amino acid sequence shown in SEQ ID NO. 2 or other sequences, which correspond to sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have similarity or homology, and so forth. None of the these nucleic acid molecule (i.e. primer) or nucleic acid molecules encoding a prostate specific membrane antigen meet the written description provision of 35 USC 112, first paragraph.

Vas-Cath Inc. V. Makurhar, 19 USPQ2d 1111, makes clear that applicant must convey with reasonable clarity to those skilled in the art, as the filing date sought, he or she was in

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possession of the invention. The invention is, for purposes of the written description inquiry whatever is now claimed (see page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed. (See Vas-Cath Inc. V. Makurhar, page 1116.).

With the exception of SEQ ID No. 2 the skilled artisan can not envision the detailed chemical structure of the encompassed polynucleotides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that is part of the invention and reference to a potential method for isolating it, The nucleic acid itself is required,. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.* 18 USPQ 2d 1016.

One can not describe what one has not conceived. See Fiddes v. Baird 30 USPQ 2d 1481, 1483.

Any inquiry concerning this communication should be directed to Dr. Anthony C. Caputa, whose telephone number is 703-308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is 703-308-0196.

Papers related to this application may be submitted to Group 1817 by facsimile transmission. Papers should be faxed to Group 1817 via the PTO Fax Center located in Crystal Mall 1. The

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faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703)-308-4242.

Anthony C. Caputa, Ph.D.

August 4, 1997



ANTHONY C. CAPUTA
PRIMARY EXAMINER
GROUP 1800